REMARKS

Claims 33-38 and 42-45 were examined and rejected. The claims have been amended as noted above. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

Claims 33-38 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Examiner states that it is unclear in **claim 33** if the means advanceable from the catheter for creating a second access penetration is the guide tube or the penetrating element or both. Applicants intend the means to refer to any structure, material or suitable entity which is advanceable from the catheter for creating a second access penetration and providing a filament path between said first and second access penetrations. Exemplary embodiments of the advanceable means include a guide tube having a penetrating element in a lumen thereof (page 7, lines 31-32). Other embodiments provide that the advanceable means can be an integral structure having a sharpened distal tip (page 8, lines 1-2). Therefore, the advanceable means may include but is not limited to any or all of the options listed by the Examiner.

The Examiner also states that in **claim 43** it is unclear as to what is meant by the guide tube has a pre-formed tip which deflects laterally. As stated in the instant application, the guide tube has a deflectable tip so that it can transition between a straight configuration and a curved configuration. The deflectable tip may be pre-formed so that it lies in a curved configuration absent constraint or external forces. Alternatively, the tip could be preformed to lie in a straight configuration. (page 9, lines 29-33; page 10, line 1). Thus, claim 43 presents such a guide tube.

Claims 33, 34, 36 and 38 were rejected under §102(e) as being anticipated by Quick et al. (USPN 5,857,999). Examiner states in part that Quick et al. describes a device for positioning a filament in a body lumen comprising a catheter (10) which can be introduced through a first access penetration into the body lumen and means advanceable from the catheter (12, 70) for creating a second access penetration. Applicants respectfully traverse such rejections.

Quick et al. describes that the Veress needle 70/introducer 10 combination is advanced through the abdominal wall 76 until it pops through the interior surface 78 of the wall, entering the abdominal cavity 80 as shown in Fig. 1 (col. 6, lines 5-8). Fig. 1A illustrates in more detail that as the Veress needle/introducer combination is advanced through the abdominal wall

76, the point 82 of the Veress needle is positioned distally of the cutting surface 66 and its point 84, so that the Veress needle point 82 penetrates first, after which the sheath point 84 follows. Because the cross-sectional area of the sheath cutting surface 66 is greater than the cross-sectional area of the Veress needle cutting surface, the sheath cutting surface 66 cuts additional tissue. (col. 6, lines 16-21). Thus, it is clear by the description of Quick et al. that one access penetration is made through the abdominal wall 76; first the access penetration has a small cross-sectional area due to penetration by the needle 70 and then the access penetration is made larger by following through the same access penetration with a cutting sheath having a larger cross-sectional area. The Examiner states that the inner cannula 12 and Veress needle 70 are "means advancable" for creating a second access penetration. Following this concept, the access penetration described above would correspond to the second access penetration. If this is the case, Applicants do not find the first access penetration into the body lumen since there is no mention of any other access penetration by the device. Thus, Applicants do not believe that the Quick et al. invention anticipates the claimed invention and **claim 33** is believed to be allowable. Likewise, Applicants believe dependent **claims 34, 36 and 38** are also in condition for allowance. However, in an effort to further prosecution, claim 33 has also been amended as described below.

Claims 33-37 were rejected under §102(b) as being anticipated by Tafeen (USPN 3,539,034). Examiner states in part that Tafeen describes a device for positioning a filament in a body lumen comprising a catheter (20) which can be introduced through a first access penetration into the body lumen and means advanceable from the catheter (12, 14, 16, 18) for creating a second access penetration and providing a filament path (12, 14, 16) between said first and second access penetrations. Applicants respectfully traverse such rejections.

Tafeen describes that the guide 20 is advanced to a position such that its bulbous end 43 abuts the tissue 50 (col. 4, lines 40-42). Then the needle support 16 and puncture stylet 18 first penetrate the paracervical space a distance of approximately one-half inch (col. 4, lines 47-51). The catheter assembly including the catheter 12 and catheter stylet 14 is then introduced into the support 16. The catheter then enters the tissue by an additional incremental amount by increasing the forward pressure on the catheter assembly (col. 4, lines 67-71). The Examiner states that elements 12, 14, 16, 18 are "means advancable" for creating a second access penetration. If this is the case, Applicants do not find the first access penetration into the body lumen since the guide 20 abuts the tissue 50. Thus, Applicants do not believe that the Tafeen invention anticipates the claimed invention and **claim 33** is believed to be allowable. Likewise,

Applicants believe dependent **claims 34-38** are also in condition for allowance. Again, in an effort to further prosecution, claim 33 has also been amended as described below.

In an effort to further prosecution of claim 33 and dependent claims 34-38, Applicants have **amended claim 33** for clarity. Amendments specify that both the first and second access penetrations are made in the lumen wall of the body lumen. Applicants believe any possible confusion over the relationship of the first and second access penetrations to the body lumen are overcome by such amendments. Thus, such amendments should be considered in relation to the above named rejections in view of both Quick et al. and Tafeen.

Claims 42-45 were rejected under §102(b) as being anticipated by Williams et al. (USPN 5,246,014). Examiner states in part that Williams et al. describes a guide tube having a proximal end, distal end, and a lumen therethrough 40 wherein the distal end of the guide tube is deflectable (col. 16, lines 1-2). Such rejections are respectfully traversed.

The Examiner directs attention to a description of the introducer 40 as having a "flexible and torque transmitting characteristic." "Torque" is defined by the Merriam-Webster's Collegiate® Dictionary, Tenth Edition, as: 1. a force that produces or tends to produce rotation or torsion, and 2. a turning or twisting force. Whereas "deflect" is defined by the Merriam-Webster's Collegiate® Dictionary, Tenth Edition, as: 1. to bend down, turn aside, and 2. to turn aside especially from a straight course or fixed direction. Thus, there is no indication that an introducer having a flexible and torque transmitting characteristic is deflectable. Further, when the distal end 52 of the catheter 50 is located in its approximate final placement position, the introducer 40 is pushed forward and then rotated so the resulting torque is transmitted to the coupler 43 which causes the tip 24 to rotate in the same direction and to engage the cardiac tissue 15 (col. 18, lines 19-28). Thus, any deflection of the introducer 40 would move the catheter 50 to another position which is would be located aside from the final placement position. This would be undesirable for the aims of the Williams et al. invention. For these reasons, Applicants do not believe that the Williams et al. invention anticipates the claimed invention and **claim 42** is believed to be allowable. Likewise, Applicants believe dependent **claims 43-45** are also in condition for allowance.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Attached is a marked up version of the changes made to the claims by the current amendment. The attached page is captioned with "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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VERSIONS WITH MARKINGS TO SHOW CHANGES MADE

33. (Amended) A device for positioning a filament in a body lumen having lumen walls, said device comprising:

a catheter which can be introduced into the body lumen through a first access penetration in the lumen wall **[into the body lumen]**; and

means advancable from the catheter for creating a second access penetration in the lumen wall and providing a filament path between said first and second access penetrations.